Paper No. 28

## UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JACK C. MURLEY and JOHN C. BRERETON

\_\_\_\_

Appeal No. 2003-0934 Application No. 08/769,596<sup>1</sup>

\_\_\_\_

ON BRIEF

Before WILLIAM F. SMITH, SCHEINER and ADAMS, <u>Administrative Patent Judges</u>.

SCHEINER, <u>Administrative Patent Judge</u>.

## **DECISION ON APPEAL**

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 8-10, the only claims remaining in the application.

Claim 8 is representative of the subject matter on appeal and reads as follows:

8. A therapeutic wound gel consisting essentially of, by weight percentage, about 88-97% water, about 0.4-0.6% carbomer, about 1.2-7.8% propylene glycol, about 0.6-1.3% glycerin, about 0.5% DMDM Hydantoin, about 0-0.95% citric acid, about 0.1% chondroitin sulfate and animal protein, and about 0-0.75% triethanolamine.

The references relied on by the examiner are:

 Andermann
 5,036,095
 Jul. 30, 1991

 Rosenthal et al. (Rosenthal)
 5,565,210
 Oct. 15, 1996

 Cornell et al. (Cornell)
 5,670,169
 Sep. 23, 1997

Claims 8-10 stand rejected under 35 U.S.C. § 103 as unpatentable over Cornell,

\_

<sup>&</sup>lt;sup>1</sup> Application for patent filed December 18, 1996.

Application No. 08/769,596

Andermann and Cornell. The examiner's Answer refers to paper no. 13 for the statement of the rejection. We reverse the examiner's rejection of the claims.

## DISCUSSION

Claim 8 is directed to a therapeutic wound gel consisting essentially of, by weight percentage, about 88-97% water, about 0.4-0.6% carbomer, about 1.2-7.8% propylene glycol, about 0.6-1.3% glycerin, about 0.5% DMDM Hydantoin, and about 0.1% of a chondroitin sulfate and animal protein. According to the specification (page 2), "about 0.1% chondroitin sulfate and animal protein" refers to a mixture of chondroitin sulfate and animal protein, present in the gel at about 0.1% by weight. The gel may also include citric acid and triethanolamine.

Cornell describes "a non-cytotoxic wound hydrating gel comprising a) a hydrocolloid mixture of sodium carboxymethylcellulose and sodium/calcium alginate, and b) and a preservative system" (column 2, lines 16-20). "Hydrocolloids which can optionally be used [] additionally . . . include Carbopol, including Carbopol 940 [at about 0.5-0.75%],<sup>2</sup> carrageenan, agar, and gelatin" while "[t]he preservative system comprises dimethylol dimethylhydantoin (DMDM hydantoin)" at about "0.05-0.1% by weight (not 0.05-1% as asserted by the examiner on page 3 of paper no. 13) and "an antimicrobial agent and a mold and yeast inhibitor" (column 2, lines 46-60). Cornell's gel is anywhere from 87-97.9% deionized water, and may also contain 0.5% triethanolamine, and as much as 10% propylene glycol or 10% glycerin. See Examples 8 and 10.

Andermann teaches that DMDM Hydantoin-containing formulations are "effective in the treatment of malconditions of the skin, including acne" and "may also be useful in

<sup>&</sup>lt;sup>2</sup> Carbopols® are acrylates/C10-30 alkyl acrylate crosspolymers, with the CTFA/INCI designation "carbomer."

Application No. 08/769,596

the treatment of burns, skin grafts and skin lacerations." "[V]arious preparations for application to the human skin [include], for example, creams, lotions, gels, ointments," etc. (column 2, lines 16-35). Example 2 describes aqueous DMDM Hydantoin-containing creams for the treatment of acne which also include 1.0-5.0% Carbopol® and 0.35-1.5% triethanolamine.

While neither reference "expressly [teaches] the . . . specific amounts of ingredients" required (paper no. 13, page 3), "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) (citations omitted).

According to Andermann, "[f]ormulations with DMDM Hydantoin . . . may contain DMDM Hydantoin concentrations of anything up to approximately 30%, depending on the intended use of the particular formulation . . . but concentrations from 0.5 percent to 10 percent by weight are preferred" (column 2, lines 45-53). We think it is fair to say that Andermann identifies the concentration of DMDM Hydantoin as a "result effective variable," and we agree with the examiner that certain of "[t]he amount[s] of ingredients [required by the claims] are similar to the prior art" (e.g., water, carbomer, propylene glycol, triethanolamine) and "the optimization of amounts of [certain other] ingredients to be employed is [] within the skill of [the] artisan" (e.g., DMDM Hydantoin). Paper no. 13, page 4.

Nevertheless, neither Cornell nor Andermann describes wound gels which additionally include chondroitin sulfate and animal protein. The examiner relies on Rosenthal to make up this deficiency, but we cannot agree that Rosenthal's teachings would have "motivated [one skilled in the art] to modify the gel or composition in [the] prior art by the addition of chondroitin and animal protein" (paper no. 13, page 4) as the examiner proposes.

Application No. 08/769,596

According to the examiner, Rosenthal "teach[es] that chondroitin sulfate and animal protein are known to be useful for wound healing." Paper no. 13, page 4. While Rosenthal does teach that "all collagen types, tenascin, laminin, chondroitin sulfate, hyaluronic acid, dermatan sulfate, heparin sulfate, heparin, elastin, fibrin, fibronectin, vitronectin, dextran, or oxidized regenerated cellulose" are suitable materials "for use in the repair of full and partial thickness defects of the skin," the materials are used in the form of a freeze-dried, bioabsorbable "fibrous mass," "sponge" or "film" which "is readily invaded by cells of the host organism," and which is "strong and resilient enough to resist collapse and may be cut and/or formed so as to conform to a wound shape so that it protects and/or fills a wound bed." Column 2, lines 37-48; and column 3, lines 1-38. The examiner has not explained how or why Rosenthal's teachings would have led one skilled in the art to include chondroitin sulfate and animal protein as integral components of a viscous, but flowable gel, and in a comparatively minor amount (about 0.1%).

As explained in <u>In re Kotzab</u>, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000):

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. [] Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." []

. . . to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. [citations omitted]

In other words, "there still must be evidence that 'a skilled artisan, . . . with no knowledge of the claimed invention, would select the elements from the cited prior art

references for combination in the manner claimed." <u>Ecolochem Inc. v. Southern</u>

<u>California Edison</u>, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000).

The initial burden of presenting a <u>prima facie</u> case of obviousness rests on the examiner. <u>In re Oetiker</u>, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Here, the evidence relied on by the examiner does not establish that all of limitations of the claims on appeal were taught or would have been suggested by the prior art. Accordingly, we are constrained to reverse the examiner's rejection of claims 8-10 under 35 U.S.C. § 103.

## **REVERSED**

William F. Smith
Administrative Patent Judge

)
BOARD OF PATENT
)
Toni R. Scheiner
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

)
Donald E. Adams
Administrative Patent Judge

)
Administrative Patent Judge

)

Paul M. Denk 763 South New Ballas Road St. Louis, MO 63141